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Newark / Philadelphia

October 10, 2025

VIA EMAIL & ECF

Honorable Michael E. Farbiarz, U.S.D.J. United States District Court, District of New Jersey United States Post Office & Courthouse, Courtroom 4 Newark, New Jersey 07101

Honorable Stacey D. Adams, U.S.M.J. United States District Court, District of New Jersey United States Post Office & Courthouse, Courtroom 9 Newark, New Jersey 07101

Hon. Douglas E. Arpert, U.S.M.J. (Ret.) Three Gateway Center 100 Mulberry Street 15th Floor Newark, New Jersey 07102

> Re: United States ex rel. Silbersher v. Janssen Biotech Inc., et al., Civil Action No. 19-12107 (MEF-SDA): CASE SCHEDULE

Your Honors:

We represent Plaintiff-Relator Zachary Silbersher. In light of the Court's recent Order denying Relator's request to set a pretrial conference and trial date (ECF 461), we respectfully request that definitive dates be set for *Daubert* and summary judgment briefing over which the parties have a dispute. (ECF 456-460) Relator invited Defendants to engage in a meet and confer to compromise on a reasonable briefing schedule, but Defendants declined, saying that they would agree to a schedule only after Judge Arpert decides Relator's motion to serve responsive reports.

As we understand it, absent an order modifying the scheduling directive set by Judge Kiel, who ordered *Daubert* motions to be filed four weeks after the close of expert discovery (ECF 213 & 270)—and which Defendants say occurred no later than October 7—initial Daubert Motions are presently **due on November 7**. Plaintiff intends to comply with that date. Any argument that the Court's longstanding orders are no longer operative because of subsequent extensions to fact and expert discovery deadlines should be rejected. Just because the Court calculated precise dates under the pre-existing timetable when it approved the parties' stipulation to extend the predicate expert discovery deadline, does not mean that the Court intended to abrogate the four-week deadline for filing *Daubert* motions after expert discovery. The date the Court approved in ECF

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Hon. Michael E. Farbiarz Hon. Stacey D. Adams Hon. Douglas E. Arpert October 10, 2025 Page 2

270 for *Daubert* motions was exactly four weeks from the then-existing close of expert discovery. This is consistent with what Judge Kiel ordered, and the parties stipulated, in ECF 213 that *Daubert* motions should be filed "four weeks" after the "close of expert discovery." Contrary to Defendants' argument, ECF 270 demonstrates that Judge Kiel understood what the parties agreed: the four-week time period continued to be the operative timeframe. For the same reason, the subsequent extensions of fact and expert discovery do not change matters, because *Daubert* motions are to be filed four weeks after that deadline.

There is one complicating factor. Relator has sent Defendants two limited supplemental expert reports responding, for the first time, to Defendants' experts. Defendants oppose allowing Relator the opportunity serve any responsive reports at all. That dispute is before the Court. Should the Court allow the responsive reports, Relator has offered virtually immediate depositions of those experts on their rebuttal opinions. As to those experts, Relator proposes that Defendants have four weeks from the completion of those depositions to file *Daubert* motions, if they choose, for those experts. The decisions on those motions could then be consolidated with the other *Daubert* motions and summary judgment, at the Court's discretion. However, this limited issue should not justify many months of delay or be grounds for Defendants to hijack the schedule to their own tactical advantage.

Finally, as to the summary judgment briefing, Defendants propose further delay by suggesting the Court bifurcate *Daubert* and summary judgment motions. That also disregards what the parties previously stipulated and Judge Kiel ordered. (ECF 213, 270) It is also inconsistent with what the Court ordered in the underlying patent infringement litigation that invalidated the subject patent in this case. (No. 2:15-cv-05909, ECF 358 at 2 & 5, providing for summary judgment briefing to be filed even before *Daubert* motions). *See also, e.g., id.*, ECF 251 (ordering summary judgment motions to be filed a month after the close of expert discovery).

Perhaps more importantly, Defendants' asserted premise for their position is clearly wrong. Defendants state, without support, that "Relator's case turns wholly on the admissibility of his experts' testimony," so it would be more efficient, they argue, to delay the schedule for many more months. (ECF 459 at 3) In fact, Relator's liability case is based principally on percipient witnesses, including 23 who have been deposed, and numerous internal documents that prove Defendants fraudulently obtained the subject patent and for years used it to unlawfully exclude generic competition. Indeed, this Court, the Federal Circuit, and three panels of the Patent Trial and Appeal Board have *already* determined that Defendants' representations to the Patent Office were false. Moreover, those courts and tribunals have ruled the patent is invalid, in part finding that Defendants' representations of a nexus between Zytiga's commercial success and the claimed

LITE DEPALMA GREENBERG & AFANADOR

Hon. Michael E. Farbiarz Hon. Stacey D. Adams Hon. Douglas E. Arpert October 10, 2025 Page 3

invention did not overcome obviousness.¹ Therefore, the only real question for liability is whether, besides being meritless, Defendants' commercial success argument was fraudulent (*i.e.*, knowingly false, deliberately ignorant, or reckless, *see* 31 U.S.C. § 37229(b)(1)). This is a scienter issue for the jury and does not depend on expert testimony, although both sides' experts may opine on related issues. As for damages, even Defendants' experts admit substantial damages (well north of \$1 billion) if the jury finds liability.

Because of this, Relator believes *Daubert* motions and summary judgment motions should be decided together, just as they were in the underlying case. Indeed, Defendants profess their belief that the *Daubert* motions may be relevant to summary judgment. Relator has no objection to the Court setting a different briefing schedule for summary judgment, but no longer than four weeks after initial *Daubert* motions are filed.

Therefore, Relator respectfully suggests that the Court set definitive dates for the foregoing motions, or, in the alternative, hold a status conference at which these issues can be discussed and decided.

Thank you very much for your consideration.

Respectfully,

/s/ Bruce D. Greenberg

Bruce D. Greenberg

BDG:emp

cc: All Counsel of Record (via ECF)

¹ See, e.g., BTG Int'l Ltd. v. Amneal Pharms. LLC, 923 F.3d 1063, 1076 (Fed. Cir. 2019); BTG Int'l Ltd. v. Amneal Pharms LLC, 352 F. Supp. 3d 352, 386 (D.N.J. 2018) (McNulty, J.); Wockhardt Bio Ag v. Janssen Oncology, Inc., No. IPR2016-01582, 2018 WL 456328, at *21 (P.T.A.B. Jan. 17, 2018).